# Backgrounder PhRMA

# **Facts About Childhood Vaccine Ingredients**

Groups challenging the safety of immunizations have raised allegations that certain Food and Drug Administration (FDA) approved ingredients in vaccines are "toxins." In many instances these allegations are completely incorrect. In others, the claims are taken out of context.

Toxins are typically defined by dose or level of exposure. Even something as benign and essential as water can be toxic if consumed in large quantities. Another example is chlorine, which can be a highly toxic chemical and was used as a weapon in World War I. Yet small amounts of chlorine are present in the tap water we drink every day. Without that chlorine, tap water would not be safe to drink.

Vaccines are extensively tested and highly regulated products. Prior to their approval by FDA for use in the market, vaccines are required to undergo significant clinical trials. These trials test the safety of all components in a vaccine. Tests are first conducted in adults and then in older children and only when safety is demonstrated in these populations will the product then be tested in young children.

**Vaccine trials are rigorous.** As examples, the recently approved vaccines for rotavirus had 70,000 children in clinical trials and the pneumococcal conjugate vaccine had close to 40,000 children.

New vaccines are evaluated for their effects in the presence of existing vaccines. Vaccines being tested in clinical trials – especially in children – are given in conjunction with vaccines already on the market. To withhold existing lifesaving vaccines from a group participating in a clinical trial would be unethical as it would leave that group of children exposed to serious infectious diseases.

Vaccines are made by weakening a natural virus or bacteria, by using a portion of the virus or bacteria, or by using an empty virus shell. The weakened product is designed to stimulate an immune response to a disease without triggering symptoms of a true infection. In addition to the "active" ingredients, vaccines may contain small amounts of other ingredients, some of which are naturally occurring in the environment and find their way into our bodies each day through a variety of sources.

Below is factual information related to the myths perpetuated about vaccine ingredients:

## **Mercury**

Preservatives prevent bacterial and fungal contamination from developing in vaccines prior to their administration and prevent contamination during complex manufacturing processes.

Thimerosal, an ethylmercury-based preservative, was used in the United States from the 1930s until 2001 to prevent contamination in some childhood vaccines. By 2001, thimerosal was no longer used as a preservative in children's vaccines. Today the only vaccine with thimerosal as a preservative that a young child in the United States might encounter is influenza vaccine and that vaccine is also available in a preservative-free version. Organizations such as the World Health Organization, the U.S. Centers for Disease Control and Prevention, the FDA, the Institute of Medicine and various medical associations have already taken a position that the alleged link between thimerosal in vaccines and autism, or other neurological disorders, is unsupported by all credible scientific evidence.

#### **Aluminum**

Adjuvants enhance and stimulate the immune system's response to vaccines, making immunizations more effective. Without an adjuvant, patients could need to receive more shots in a vaccine series or face lower immunity and less protection from disease. The most common adjuvant in vaccines is aluminum, a natural element found in the environment that has been used safely in vaccines for 75 years. Aluminum is in food, water, infant formula and even breast milk.

### **Formaldehyde**

Formaldehyde can be used as an antimicrobial. Formaldehyde effectively inactivates the organisms and biological substances used in vaccines. Formaldehyde is present in the environment and is a byproduct of metabolism so it is already present in the human body.

# **Addressing False Claims**

#### **Antifreeze**

There is no antifreeze in vaccines. A single component of antifreeze – polyethylene glycol – is used to inactivate the flu virus in one brand of that vaccine; it is also used in the purification of certain vaccines. This chemical is also widely and safely used in personal care products, such as skin creams and toothpaste.

# **Other Ingredients**

Claims have been made that various substances used to support the growth of viruses used in vaccines are present in the final vaccine product. This is untrue and is akin to saying there are trees in apple juice just because the apples originated on trees. In the case of vaccines, viruses are grown initially in cell lines of various types. Then, the viruses are harvested and go through multiple processing and purification steps over months of time before the final product is ready for use.

Below are facts about the specific allegations raised:

#### **Aborted Human Fetus Cells**

Vaccines do not contain human cells or tissue. Human cell lines are used in the early stages of production of some vaccines because viruses need a living cell in which to grow. These cell lines were derived from fetal tissue more than 40 years ago. The same two cell lines are reproduced and used repeatedly so that no new fetal tissue is required in the ongoing production of vaccines. As with all viral vaccines, multiple purification steps ensure that cells are not in the final vaccine product.

## **Chick Embryos**

There are no chick embryos in vaccines. Many influenza vaccines begin with viral growth in chicken eggs and then undergo multiple purification steps. Some residual egg proteins may be present in the final vaccine product. Chicken eggs and their proteins are routinely consumed as part of the human diet.

## **Monkey Kidneys**

There are no monkey kidneys in vaccines. Monkey kidney tissue is used to support the growth of certain viruses for making vaccines; for example, it was used to support the growth of the weakened polio virus that went into the oral polio vaccine. Multiple purification steps ensure that no kidney cells are present in the final product.

#### **Fetal Bovine Serum**

When viruses are growing in cells, they need a source of nutritional ingredients. In some instances fetal bovine serum is the source of these growth factors. Once the viruses are harvested, they undergo multiple processing and purification steps before the final product is released to the market.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated \$44.5 billion in 2007 in discovering and developing new medicines. Industry-wide research and investment reached a record \$58.8 billion in 2007.

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